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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,818

01/15/2004

Karen M. McNally-Heintzelman

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BOSE MCKINNEY & EVANS LLP
JAMES COLES
135 N PENNSYLVANIA ST
SUITE 2700
INDIANAPOLIS, IN 46204

EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,818

Applicant(s)

MCNALLY-HEINTZELMAN ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5-3-04, 7-21-04, 12-20-06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment and remarks, filed 4/11/2007, have been received. Claims 1 – 13 are pending in this action.

Election/Restrictions

Applicants' argument with respect to the restriction requirement between Groups I and II has been considered and is persuasive. The requirement is **withdrawn** and Group II is hereby **rejoined**.

Applicants' elected the species of green food coloring as the light absorber. Claims 11 and 12 do not read on the elected species, and as such are **withdrawn** from consideration. Claims 1 – 10 and 13 are considered on the merits below.

Priority

It is noted that this application is a CIP of 10/610,068, filed 6/30/2003, which claims benefit of 60/442,64, filed 1/24/2003. However, the '068 Application is drawn to composites that are not light activated, as opposed to instant claims which are drawn to light activated components. Since the parent application does not have an enabling description of the pending claims, the effective filing date of instant Application is the actual filing date of 1/15/2004. The various intervening references cited below are competent prior art under appropriate sections of 35 U.S.C. 102.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 – 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Riley et al., Biomed Sci Instrum (37) 451 – 456, 2001.

Riley discloses a surgical adhesive composition comprising a PLGA scaffold doped with a protein solder, the protein solder being a mix of porcine serum albumin and indocyanine green dye (ICG) (abstract). PLGA is the scaffold material of claims 1, 5, and 6. Since it is made by film-casting (see section 2.1), the scaffold is understood to have at least one irregular surface. ICG is the light absorber of claims 3, 4, and 6 (ICG is used as a diagnostic agent, and thus is a “photosensitive pharmaceutical”). Claims 1 and 2 recite changes in the tensile strength upon applying light energy to the composite. These changes are understood to be inherent, since the same composition necessarily has the same properties, and also as evidenced by McNally et al. “ICG Doped Protein Solders for Improved Tissue Repair”, of record. The property of the composition recited in claim 8 is also deemed to be inherent, since the same composition necessarily has the same properties.

Claims 1 – 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by McNally et al in Journal of Biomedical Optics 6(11) 68 – 73, January 2001.

McNally teaches a surgical adhesive material comprising a PLGA scaffold doped with bovine serum albumin and indocyanine green dye. PLGA is the scaffold material of claims 1, 5 and 6. It is made by film-casting and leaching (materials and methods section), and so is understood to have irregular surfaces. ICG is the light absorber of claims 3, 4, and 6 (ICG is used as a diagnostic agent, and thus is a “photosensitive pharmaceutical”). Claims 1 and 2 recite changes in the tensile strength upon applying

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light energy to the composite. Another property of the composition recited in claim 8. It is understood that since the McNally reference teaches compositions with the same components as the claims that the reference's compositions will also have the same properties.

Claims 1 – 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Moser et al. "New Range of Light-Activated Surgical Adhesives for Tissue Repair", Biomed Sci Instru, 37, 441-449, 2001.

Moser discloses a surgical adhesive for laser assisted tissue repair, comprising a polymer scaffold doped with serum albumin and a chromophoric dye (light absorber) (Abstract). The scaffold is a porous PLGA scaffold, as in claims 1, 5, and 6. The chromophoric dye is ICG, the light absorber of claims 3, 4, and 6 (ICG is used as a diagnostic agent, and thus is a "photosensitive pharmaceutical"). The light absorber is used in concentrations as high as 2.5mg/mL deionized water (equivalent to 192 ug/13 mL, or "about 200" as required by claim 9, see Fig. 1 and Materials and Methods section). Claims 1 and 2 recite changes in the tensile strength upon applying light energy to the composite. These changes are understood to be inherent, since the same composition necessarily has the same properties, and also as evidenced by McNally et al. "ICG Doped Protein Solders for Improved Tissue Repair", of record. The property of the composition recited in claim 8 is also deemed to be inherent, since the same composition necessarily has the same properties.

Claims 1 – 10 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoffman et al., Biomed Sci Instrum 2003; 39:12-17, 2003.

Note that the USPTO has determined the earliest public availability date of this reference to be April, 2003.

Hoffman discloses a surgical adhesive composition comprising serum albumin, deionized water, various concentrations of chromophore, and porous PLGA scaffolds made by solvent casing and particle leaching (materials and methods). The chromophores used were ICG, Methyl Blue (MB – a pH indicator), blue food coloring, and green food coloring (table 1). The green food coloring was used in various concentrations, including at least one sample at about 600 uL per 13 mL of deionized water (Figure 1, right side). Claims 1 and 2 recite changes in the tensile strength upon applying light energy to the composite. These changes are understood to be inherent, since the same composition necessarily has the same properties, and also as evidenced by McNally et al. "ICG Doped Protein Solders for Improved Tissue Repair", of record. The property of the composition recited in claim 8 is also deemed to be inherent, since the same composition necessarily has the same properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moser et al.

The teachings of Moser are discussed above.

What is lacking is a teaching of a light absorber concentration of about 600 ug per 13 mL of water.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to alter the concentration of the light absorber in order to find the optimal concentration. Moser teaches that the concentration of light absorber is optimizable, in that Moser tries several concentrations of this component. It is generally considered obvious to optimize a parameter that is known to be optimizable and results-effective. Since behavior of light absorbing materials follows predictable patterns when their concentration is changed (such as Beer's Law), the artisan would enjoy a reasonable expectation of success.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Byrd et al., "Absorption properties of alternative chromophores for use in laser tissue soldering applications", 2003; Davis et al., Optimization of Laser-solder repair technique for possible application in strabismus surgeries, Biomed Sci Instrum 2002, 351 – 356; Soller et al., Use of Infrared temperature monitoring system to determine optimal temperature for laser-solder tissue repair, Biomed Sci Instrum 2002 339 – 344; Hoffman et al., Biodegradable synthetic polymer scaffolds for reinforcement of albumin protein solders used for laser assisted tissue repair Biomed Sci Instrum 2002, 339 – 344; Brooks et al., Exogenous chromophore for the argon and Nd:YAG lasers: a potential application to laser tissue interactions Lasers in Surgery and Medicine 1992, 294 – 302; Birch et al., Methylene blue based protein solder for vascular anastomoses: an in vitro burst pressure study Lasers in Surgery and Medicine 2000, 323-329; Wang et al., New Technique for Laryngotracheal mucosa transplataion Arch Otolaryngol Head Neck Surg/ Vol 121 July 1995 773 – 777; Wadia et al., Sutureless liver repair and hemorrhage control using laser-mediated fusion of human albumin as solder, J. Trauma. 2001 51 – 59; McNally et al., Photothermal effects of laser tissue soldering, Phys Med Biol 1999 983 – 1002; McNally et al., Novel solid protein solder designs for laser-assisted tissue repair, Lasers in Surgery and Medicine, 2000, 147 – 157; Sorg et al., Laser-tissue soldering with biodegradable polymer films in vitro: film surface morphology and hydration effects, Lasers in Surgery and Medicine 2001, 297-306; Poppas et al., Patch Graft Urethroplasty using dye enhanced laser tissue welding with a human protein solder: a preclinical canine model, J Urology 1993, 648-650; Xie et

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al., Laser welding with an albumin stent: experimental ureteral end to end anastomosis,

Lasers in Surgery, 2000, 215 – 220.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
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MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600